

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY
PATENT LITIGATION

MDL No. 1592 (MLW)

This Document Relates To All Actions

**JOINT REPORT TO THE COURT
PURSUANT TO ORDER DATED NOVEMBER 5, 2004**

In its November 5, 2004 Memorandum and Order ("Order"), the Court asked the parties to meet and confer, and report, on a set of questions recited on pages 31 and 32 of the Order. Below are responses to the Court's questions from each of the parties to this multidistrict litigation except for Genentech, Wyeth, and Genetics Institute. Genentech, Wyeth, and Genetics Institute have chosen to file separate reports.

The following shorthand references will be used to refer to individual cases:

"Amgen" refers to *Immunex Corp. and Amgen, Inc. v. Columbia University*, Case No. 04cv10740 MLW, previously Case No. 03cv4349 MRP (C.D. Cal.)

"Biogen" refers to *Biogen, Inc., Genzyme Corp., and Abbott Bioresearch Center, Inc. v. Columbia University*, Case No. 03cv11329 MLW

"Wyeth" refers to *Wyeth and Genetics Institute LLC v. Columbia University*, Case No. 03cv11570 MLW

"Johnson & Johnson" refers to *Johnson & Johnson v. Columbia University*, Case No. 04cv10743 MLW, previously Case No. 03cv8811 BSJ (S.D.N.Y)

"Genentech" refers to *Genentech, Inc. v. Columbia University*, Case No. 04cv11546 MLW, previously Case No. 04cv1910 VRW (N.D. Cal.)

A. Whether the parties agree that all of the claims listed in Columbia's Proposed Order to its Motion To Dismiss should be dismissed pursuant to the Court's Order?

1. *Amgen*

a. Position of Amgen and Immunex

Amgen does not agree with Columbia's Proposed Order.

The following claims in Amgen's current pleading (the Second Amended Complaint, filed December 10, 2003) are not resolved by the Court's November 5, 2004 Order:

- Amgen's request for a declaration that additional royalties are not due under the parties' license agreement for periods after August 16, 2000, entirely apart from the issue of the validity or enforceability of the '275 patent (First Claim for Relief); and
- Amgen's request for a declaration that Columbia's misconduct in connection with the events leading to and concerning the Axel patents constitutes "repressive practices" in breach of the license agreement, such that *inter alia* "payment of the royalties claimed by Columbia is excused" (Seventh Claim for Relief).¹

Neither of these is mooted by Columbia's agreement not to assert the '275 patent against Amgen in the future. The First Claim for Relief is, among other things, the counterpart of Columbia's written demands, and later counterclaims, for royalties, seeking a declaration that none are owed; it is as valid a claim as Columbia's claim for those royalties, which Columbia admits still presents a case or controversy. The Seventh Claim for Relief – as to which Columbia's motion to dismiss on a variety of grounds or for more definite statement was *denied* by the transferor court – seeks contractual relief (including excusing any obligation to pay the claimed royalties) because Columbia's past conduct constituted "repressive practices" within the meaning of the parties' agreement.²

Columbia's later covenant not to sue does not erase from history its own past breaches of the contract. And Amgen's claims are not limited to Columbia's recent conduct concerning the '275 patent after it issued, or Columbia's unlawful requests for royalties based on pending applications, but include *conduct leading to the '275 and other Axel patents* as alleged in great detail in the Second Amended Complaint. *See, e.g.*, Second Amended Complaint at ¶¶ 22-58, incorporated by reference into Amgen's First and Seventh Claims for relief; *id.* at ¶ 58 ("Columbia has . . . Made demand upon Amgen and Immunex in the name of the License Agreement for the payment of royalties for sales occurring after August 16, 2000, even though the '216, '665 and '017 patents had expired."). This conduct,

¹ Columbia's argument below is based on a fundamental misconception that these counts "pertain solely to Amgen's obligations to pay royalties on product manufactured *after* August 16, 2000." There is no such limitation in the counts, which do not mention manufacturing dates. These claims relate to payments of royalty that Columbia contends should have been paid on sales after August 16, 2000 – the royalties Columbia is claiming in this case.

² The license agreement between Columbia and Amgen – like most if not all of the other Columbia licenses – incorporates by reference the obligations Columbia was required to assume to the United States in order to obtain an assignment of the technology in question. One of those obligations is to refrain from "repressive practices." *See* Second Amended Complaint, Exhibit E, at § 2(b) and Appx. A thereto, conditions (j) and (l). Accordingly, Columbia's misconduct leading to the '275 patent and other Axel patents is relevant to the ongoing issue of Columbia's performance under the license agreement. Columbia does not dispute that there are ongoing disputes between the parties in this action regarding their performance and duties under that agreement.

which led to the '275 and other Axel patents, remains contractually relevant: as explained by Amgen in opposition to Columbia's unsuccessful motion to dismiss, "Columbia's repressive practices occurred over a period commencing in the 1980's, including conduct well before Amgen ceased paying royalties. Material non-performance on Columbia's part excuses later duties of Amgen, whether or not Columbia's non-performance was yet known. RESTATEMENT (SECOND) OF CONTRACTS (hereinafter "Restatement"), at § 225 cmt. e." Memo. of Pts. and Auths., filed Jan. 12, 2004, p. 9 n. 6.

If the Court is inclined to address Columbia's renewed remand motion, Amgen requests a schedule be set for briefing that issue, following the Court's determination on what issues remain in these actions. Until that is determined, it is difficult for the parties to address or the Court to decide issues regarding remand.

The issue of remand was premature in Columbia's motion to dismiss, and was not fully briefed by either Columbia or the other parties, pending a determination of claims surviving in the consolidated MDL actions. The briefing on Columbia's motion to dismiss focused on Columbia's then-defective Covenant, rather than the effect of Columbia's later-expanded Covenant on the parties' contractual claims and defenses, which were neither fully briefed in Columbia's motion nor, accordingly, in the oppositions.³ The relevance of Columbia's alleged acts of misconduct not only to its patent rights *but also to the parties' contractual rights* has not yet been the subject of full briefing to this Court for review.

We do not understand the Court's November 5, 2004 order to mean, as Columbia now argues, that the Court intended to dismiss all the contractual claims even though they were not briefed; indeed, if the Court had so intended, there would be no need for this further report on what claims are and are not affected by the Court's ruling. Indeed, whether or not Amgen's Seventh Claim for Relief ever existed, Columbia's repressive practices, as alleged by Amgen, are squarely put at issue in this case by Amgen's denial of Columbia's allegation that it performed all obligations on its part to be performed,⁴ and the Court should be advised regarding those issues before ruling on Columbia's renewed motion to remand. Nor have the plaintiffs' affiliates' claims regarding the '275 patent itself been presented, as would be proper in separate new actions. See Transcript of Oct. 6, 2004, at 131. Given that "remand . . . prior to the completion of . . . pretrial proceedings [occurs] only upon a showing of good cause," *In re South Central States Bakery Products Antitrust Litigation*, 462 F. Supp. 388, 390 (J.P.M.L. 1978), this issue deserves briefing beyond the scope of this report.

³ The Court was, however, advised that Amgen was seeking contractual declaratory relief regarding royalties "whether by reason of pending patent applications or otherwise" (Memo. of Amgen et al. in Opposition to Columbia's Emergency Motion to Dismiss, at 14) and that the parties have contract claims that would survive the Covenant, and the Court discussed whether such claims should be stayed. See, e.g., Transcript of Oct. 6, 2004 Hearing at 117.

⁴ See Columbia Counterclaims, ¶¶ 15, 19, and denied entirely in Amgen's Reply. One of Columbia's obligations was to refrain from repressive practices, and its pattern of conduct leading to and involving the Axel patents breached that obligation.

Furthermore, Amgen has advised Columbia that it proposes to amend its complaint to reflect certain relevant events that have occurred since the filing of its current complaint, and to expand certain claims for relief based on facts that have come to light since that time. These events and facts include:

- Columbia's purported termination of its license agreement with Amgen on March 9, 2004;
- The recent revelation that Columbia granted at least one other licensee, Genetics Institute, a more favorable royalty rate than it granted to Amgen, entitling Amgen to relief under the "most favored nation" royalty provision of its license at issue in this action, and discovery of overpayments by Immunex Corporation to Columbia under its license at issue in this action;
- A continued pattern of misconduct by Columbia – including its application to reissue the '275 patent – that forms further evidence of its "repressive practices," which are relevant to Columbia's performance under its license agreement with Amgen and therefore to Amgen's request for a declaration that additional royalties are not due under the parties' license agreement, and to Amgen's claim that this is an exceptional case;
- Certain revelations, during recent Court-ordered discovery of witnesses to preserve testimony and through related investigation, showing that Columbia committed misconduct in procuring the Axel patents that expired in 2000 (the "prior issued Axel patents"), thus providing additional support for Amgen's claims.

If the Court allows a motion, which Amgen will present promptly, to make these amendments,⁵ then the following claims in Amgen's proposed Third Amended Complaint will survive the Court's ruling of November 5:

- Amgen's request for a declaration that additional royalties are not due under the parties' license agreement, entirely apart from the issue of the validity or enforceability of the '275 patent, and indeed that Amgen should recover back royalties overpaid by mistake (First Claim for Relief);
- Amgen's request for a declaration that Columbia's misconduct in connection with the prior issued Axel patents renders them unenforceable and that

⁵ Columbia advised Amgen on December 2, 2004, that it will not agree to any amendments. Columbia cites below to portions of the Court's words on October 6 that amendment of pleadings should not occur pending the decision on the motion; but that was a discussion of *how to bring claims on behalf of Amgen affiliates* and there was no discussion of precluding amendments by existing parties to their contract-related claims. The Court stated that "if there's what you call an affiliate that's not a party to this case and if I dismiss this case, then that affiliate can file its own case the way Idec did." Transcript, Oct. 6, 2004, at 131.

Columbia cannot claim royalties under them, together with Amgen's request for a declaration that this is an exceptional case and for an award of attorneys' fees on that basis (Third Claim for Relief); and

- Amgen's request for a declaration that Columbia engaged in "repressive practices" within the meaning of the license agreement (Seventh Claim for Relief).

b. Position of Columbia

Columbia's Counterclaims. The parties agree that Columbia's counterclaims against Amgen should *not* be dismissed. Columbia's counterclaims are not patent claims; they are, rather, contract claims seeking more than \$125 million in back royalties and interest under the original Axel patents for product manufactured *before* August 16, 2000, during the term of the original Axel patents. Columbia's counterclaims against Amgen have nothing to do with the later-issued '275 patent and have nothing in common with any claim made by or against any other plaintiff. The Court's November 5, 2004 Order does not affect Columbia's counterclaims in any way, and these claims are now ripe for remand to the Central District of California (as explained more fully in Columbia motion to dismiss and reply brief).

Amgen's Declaratory Relief Claims. The parties disagree, however, with respect to the resolution of Amgen's affirmative declaratory relief claims. Amgen now asserts that its First and Seventh Claims for Relief should not have been dismissed, arguing for the very first time in this case that these claims somehow pertain to Columbia's *original three Axel patents*, all of which expired more than four years ago, on August 16, 2000. Amgen further proposes to amend its Second Amended Complaint and thereby file its *fourth* pleading in this action, a proposal the Court explicitly rejected at the October 6, 2004 hearing on Columbia's motion.

On September 2, 2004, Columbia moved for the dismissal of each and every one of Amgen's affirmative claims for relief. In opposing that motion, Amgen argued that even if the Court were to find that Columbia's covenant extinguished subject matter jurisdiction as to the '275 patent, the Court would still have jurisdiction over two of Amgen's claims: 1) Amgen's claim for attorney's fees under 35 U.S.C. § 285; and 2) Amgen's First Claim for Relief. As to the First Claim for Relief, Amgen argued that it should survive because it "seeks a declaration whether any royalties are owed after August 2000 under the parties' contract, whether by reason of pending patent applications or otherwise." Amgen Opp. at 14.

The First Claim for Relief and the attorney's fees claim were the *only* claims that Amgen ever urged should survive in the event the Court found that Columbia's covenant vitiated this Court's subject matter jurisdiction. The Court expressly rejected both of these arguments. The Court ruled "there is no risk that [any plaintiffs] will be required to pay Columbia damages for their current activities or products even if the '275 patent is reissued with new or amended claims," and that therefore "the reasons for the Declaratory Judgment Act no longer pertain to this case." Order, at 18. Additionally, the Court rejected Amgen's Section 285 claim for attorney's fees. Order, at 29-30.

At no time did Amgen ever suggest, as it does now for the very first time, that *any* of its declaratory relief claims pertained to Columbia's expired, original Axel patents, nor did Amgen ever assert that its *Seventh* Claim for Relief should also survive Columbia's motion to dismiss. Indeed, Amgen's Seventh Claim for Relief is not discussed *anywhere* in Amgen's opposition papers, and was never even mentioned by Amgen's counsel during any of his lengthy remarks at the October 4, 2004 hearing on Columbia's motion to dismiss. Despite its failure in this regard, Amgen chooses not to say even a single word in its portion of this Joint Report in explanation of its conduct, as if this Court routinely permits parties to present new arguments in opposition to a motion *after* the motion has already been ruled upon.

Having failed to make *any* of these arguments about the supposed scope of the First and Seventh Claims for Relief until *after* this Court had already granted Columbia's motion, Amgen's effort to transform and resuscitate these claims should be flatly rejected not only as untimely, but also as fundamentally unfair both to the Court and Columbia.⁶

Indeed, both the First and Seventh Claims for Relief pertain solely to Amgen's obligations to pay royalties on product manufactured *after* August 16, 2000 (the date the three original Axel patents expired) based either upon pending patent applications or the issued '275 patent. Columbia has now unequivocally confirmed that it is not seeking any such royalties as to the '275 patent as it currently reads, or any claim of a reissued or reexamined '275 patent that is identical or substantially identical to any claim of the '275 patent.

Nor is Amgen assisted by paragraph 58 of its Second Amended Complaint, from which Amgen selectively quotes, above. This paragraph simply proves Columbia's point. In that paragraph, Amgen expressly and specifically links Columbia's alleged demand for post-expiration royalties, in paragraph 58(a), to the *pendency of certain patent applications*. *See*, Second Amended Complaint, paragraph 58(b), alleging that Columbia "[a]sserted to Amgen and Immunex in this regard, inter alia, that Columbia had pending patent applications after August 16, 2000, *as a result of which Columbia demanded that Amgen pay royalties on sales after August 16, 2000.*") Those applications are no longer at issue, because Columbia abandoned any such claim to royalties on the basis of pending patent applications more than a year ago, as Amgen admits. Nothing anywhere in the Second Amended Complaint, let alone in paragraph 58, can be read to suggest that Amgen's pleading pertains to royalties payable under the original Axel patents. If that was Amgen's

⁶ Before the MDL transfer, District Judge Pfaelzer *twice* entertained motions by Columbia to dismiss the Seventh Claim for Relief, granting the first motion to dismiss without prejudice, and denying the second. In her second order, Judge Pfaelzer expressly cautioned Amgen that "[a]lthough this Court will remain open to further evidence and argument, review thus far suggests that *Plaintiffs' Seventh Claim is unlikely to survive a dispositive motion.*" Memorandum of Decision entered January 29, 2004, at 6 (emphasis supplied). Judge Pfaelzer's familiarity with the scope of Amgen's Seventh Claim for Relief—an issue never briefed for this Court—is yet another reason why this Court should suggest a remand to the Central District of all remaining claims in the *Amgen* litigation.

position, they should have stated it in a timely manner in opposition to Columbia's motion to dismiss.

Whatever Columbia's position may once have been, it could now not be more clear that Columbia is not seeking from Amgen, and will not ever seek, any royalties on the '275 patent, on any pending patent application (unless and until it matures into an issued patent), or on any claim of any reissued or reexamined '275 patent that is identical or substantially identical to any claim of the '275 patent. The Court should therefore confirm that Amgen's First and Seventh Claims for Relief are dismissed.

Amgen's Proposal to Amend. With respect to Amgen's proposal that it be permitted to file a fourth pleading in this action, Columbia believes this would be unjustified, untimely and improper, coming as it does *after* the dismissal of Amgen's declaratory relief claims. Indeed, when Amgen raised the issue of an amended pleading to add the claims of Amgen's affiliates at the October 6, 2004 hearing, the Court specifically rejected any such filing as untimely and told Amgen it could not move to amend. 10/6/04 Hearing, at 130-131.⁷ If it is too late for Amgen to amend its pleadings to bring in new claims by new parties, then it inexorably follows that it is too late for an *existing* party to file what would be its *fourth* pleading in this matter.

Remand. Finally, Amgen asserts that it should be permitted another round of briefing on the issue of Columbia's request for a suggestion of remand as to all remaining claims. Columbia's motion was directed to each and every one of Amgen's affirmative claims for declaratory relief, and Columbia's motion specifically requested remand solely with respect to Columbia's counterclaims against Amgen. Amgen should not be heard to complain now, as it does above, that the issue of Amgen's contract claims was "premature" and "not fully briefed." That was a decision unilaterally made by Amgen, at a time when they were on notice of the scope of Columbia's motion and the relief requested therein. Amgen should not be permitted to sit on its hands until the Court rules on Columbia's motion, and only then protest that it hasn't yet "fully briefed" the issue.

2. *Biogen*

a. Position of Biogen and Genzyme

Biogen Idec MA, Inc. ("Biogen") and Genzyme Corporation ("Genzyme") agree that, pursuant to the Court's Memorandum and Order of November 5, 2004, and provided that Columbia complies with its Covenant Not to Sue dated October 12, 2004, Counts II, III, and IV of the complaint in their original action (No. 03-CV-11329-MLW) ("*Biogen* action") should be dismissed.

Count I, which seeks a declaration under the License Agreements, should not be dismissed as to Biogen and Genzyme. The declaration Biogen and Genzyme seek, that no

⁷ "THE COURT: No, at this point you [Mr. Hasson] can't move to amend. You've had the briefing and the motion to dismiss.... So I'm going to decide the case on the record as it now stands." 10/6/04 Hearing, at 130-131.

royalties were owed at the time Columbia wrongfully terminated their licenses, is not moot, because Columbia used Biogen's and Genzyme's nonpayment as justification to terminate their licenses. Biogen and Genzyme then incurred very significant damages by reason of the wrongful terminations. Further, certain of the claims asserted in *Biogen Idec Inc., Biogen Idec MA, Inc. and Genzyme Corp. v. The Trustees of Columbia University in the City of New York*, Civ. Action No. 04-CV-12009-MLW ("*Idec* action"), arise out of the wrongful terminations.

Columbia is mistaken in arguing that Count I does not plead a justiciable controversy. The question is not, as Columbia puts it, whether there is a "reasonable apprehension" of suit. Rather, the question is whether Biogen and Genzyme owed any royalties to Columbia under the '275 patent at the time Columbia used their nonpayment of royalties as a justification to terminate their licenses.

Columbia makes much of the fact that Abbott, also a plaintiff in the *Biogen* action, agrees to the dismissal of Count I *as to Abbott*. Columbia ignores the fact that Abbott's situation is materially different from Biogen and Genzyme's, as are the situations of each of the other declaratory judgment plaintiffs in this multidistrict litigation. In particular, Biogen and Genzyme suffered significant damages when they moved for a preliminary injunction to prevent Columbia's unlawful termination of their licenses. In ruling on that preliminary injunction motion, this Court recognized that Biogen and Genzyme had demonstrated a high likelihood that the '275 patent was invalid. Indeed, after terminating plaintiffs' licenses on the basis of royalties owed under the '275 patent, Columbia later unilaterally restored Biogen's and Genzyme's licenses, thus implicitly acknowledging that the termination had been wrongful. However, neither Abbott nor any other plaintiff took steps such as those taken by Biogen and Genzyme to prevent the wrongful termination of their licenses. Thus, no other plaintiff incurred the damages Biogen and Genzyme incurred.

Because adjudicating Count I will primarily involve issues of patent law (*i.e.*, the validity and enforceability of Columbia's U.S. Patent No. 6,455,275), Biogen and Genzyme continue to seek both a declaration that the *Biogen* action is "exceptional" under 35 U.S.C. § 285 and an award of fees. Count V of the *Biogen* action, therefore, also should not be dismissed.

For the sake of efficiency and economy, Biogen and Genzyme are willing to stipulate to the dismissal of all claims in the *Biogen* action on the condition that they are permitted to proceed with Counts I and V as part of the *Idec* action. Alternatively, Biogen and Genzyme are willing to move to supplement the original *Biogen* action with the new claims currently pending in the *Idec* action if the Court regards that course of action as preferable. Either alternative would eliminate the need for the Court to rule on two pending motions: (i) the motion of Biogen and Genzyme to consolidate the *Idec* action with the original *Biogen* action (No. 03-CV-11329-MLW, Court's Docket No. 89), and (ii) Columbia's motion to dismiss the *Idec* action without prejudice (No. 04-CV-12009, Court's Docket No. 6). Columbia has been unwilling to discuss either alternative. Instead, it takes the contradictory positions that all counts of the *Biogen* action should be dismissed, and also that Biogen and Genzyme should move to supplement the *Biogen* action rather than proceed with the *Idec* action.

Columbia's arguments concerning the propriety of the *Idec* action merely repeat Columbia's briefing on the pending motions concerning the *Idec* action. Biogen and Genzyme will not detain the Court by repeating here what is set forth in their briefs. To the extent Columbia is arguing that amendment after final judgment is disfavored, those arguments are irrelevant, because no final judgment should be entered in this case.

b. Position of Abbott

Abbott agrees that all of the claims asserted by Abbott in *Biogen I* that are listed in the Proposed Order should be dismissed without prejudice pursuant to the Court's Order. The parties therefore agree that there are no remaining counts between Abbott and Columbia and that Abbott's case should be dismissed without prejudice pursuant to the Court's November 5, 2004 Order.

c. Position of Columbia

Columbia maintains that all claims in the *Biogen I* Amended Complaint have been dismissed by the November 5 Order. There are three co-plaintiffs in the *Biogen I* action, Biogen, Genzyme and Abbott, and each of these plaintiffs asserted the identical claims against Columbia. Abbott agrees with Columbia that all claims as to Abbott in the Amended Complaint are dismissed. Biogen and Genzyme contend that Count I of the Amended Complaint, which seeks a declaration that plaintiffs "have no obligation to pay . . . royalties because . . . the '275 patent is invalid and unenforceable," is not dismissed.⁸ As the only relief sought in Count I is a declaration that no royalties are owed because the '275 patent is invalid and unenforceable, this claim for relief has been dismissed pursuant to the November 5 Order.

3. *Genentech*

a. Position of Columbia

Columbia maintains that all claims in the *Genentech* complaint are dismissed except for the Fifth claim for relief.

Columbia invited Genentech to submit a statement for this Joint Report. However, Genentech has refused to do so and apparently intends to submit its own independent report. Because Columbia believes that filing separate reports is inconsistent with the Court's Order, Columbia has included its position on the *Genentech* litigation in this Joint Report.

4. *Wyeth*

a. Position of Columbia

⁸ Because Biogen and Genzyme contend Count I is not dismissed, they also contend that Count V, which seeks a declaration under 35 U.S.C. § 285, is not dismissed. Columbia submits that Count V has been dismissed, just as Count I has been dismissed

Columbia maintains that all claims in the *Wyeth* complaint should be dismissed. Wyeth and its subsidiary Genetics Institute (collectively, "Wyeth") maintain that the Fourth, Fifth and Sixth Claims for relief should not be dismissed. Wyeth's Fourth and Fifth Claims seek declarations that no royalties or annual fees are owed based on the '275 patent, or any pending applications included in its license agreement with Columbia. Wyeth's Sixth Claim seeks a declaration that the '275 patent is unenforceable due to patent misuse because Columbia demands royalties and fees based on the '275 patent and based on the application that matured into the '275 patent.

On March 9, 2004, Columbia committed in writing not to seek royalties from Wyeth (and all the other plaintiffs) based on pending patent applications (unless and until they mature into an issued patent). Columbia has also covenanted not to sue Wyeth based on the '275 patent. In light of these covenants, Wyeth has no reasonable apprehension of being sued based on the '275 patent or based on any pending patent applications included in its license agreement. Because of the lack of reasonable apprehension of suit, Wyeth's Fourth, Fifth and Sixth Claims cannot satisfy the requirements of the Declaratory Judgment Act.

Having lost the motion to dismiss, Wyeth now contends that its Fourth, Fifth and Sixth Claims are not declaratory judgment claims at all, but instead direct claims for relief. This position is not supported by the text of the claims. They are all plead as traditional declaratory judgment claims, coupled with requests for further relief under 28 U.S.C. § 2202. However, relief under § 2202 can only be granted after the entry of a declaration, which cannot occur here because Wyeth cannot satisfy the jurisdictional requirements of the Declaratory Judgment Act. If Wyeth wanted to bring direct claims against Columbia for breach of contract and other conduct, it should have pleaded them before their claims were dismissed. It is unfair to Columbia and this Court for Wyeth to make their claims a moving target in an effort to avoid the consequences of the November 5 order.

Wyeth appears to believe that it mistakenly paid certain royalties to Columbia under the original Axel patents (the predecessors to the '275 patent). Wyeth apparently wants to maintain the Fourth, Fifth and Sixth Claims to effectuate the return of these royalties. However, Wyeth cannot use the Fourth, Fifth and Sixth Claims for this purpose because these claims relate solely to royalty obligations based on pending patent applications and the '275 patent, and Columbia has covenanted not to assert either of these positions as a basis for either collecting or refusing to refund royalties. In any event, Columbia has asked Wyeth to provide it with certain technical information regarding the production of the product at issue sufficient to establish that the royalty payment at issue was not owed. If and when it receives this information, Columbia anticipates the dispute can be resolved.

Wyeth has also made reference in the meet and confer to additional "funds" that were paid to Columbia based on conduct occurring after August 2000 that it wants repaid. Wyeth contends the repayment of these funds serves as a basis for the continuing vitality of the Fourth, Fifth and Sixth Claims. Wyeth appears to be referring to license fee payments that it made in 2001. This cannot serve as a basis for retaining jurisdiction for two reasons: (1) Wyeth's request is moot because its license agreement included the '636 patent. Regardless of whether Wyeth is required to pay license fees based on pending applications or the '275

patent, it is required to pay based on the '636 patent. (2) The November 5 Order concludes that the Court will exercise its discretion to dismiss declaratory judgment claims based on annual license fee payments.

Wyeth has indicated that it will move for leave to amend its complaint to seek damages based on Columbia's conduct occurring before the November 5 Order. As discussed below in the context of *Biogen*, it is improper to seek to amend a complaint after it has been totally dismissed based on facts that were known prior to dismissal. Columbia intends to oppose this motion.

Columbia invited Wyeth to submit a statement for this Joint Report. However, Wyeth has refused to do so and intends to submit its own independent report. Because Columbia believes that filing separate reports is inconsistent with the Court's Order, Columbia has included its position on the *Wyeth* litigation in this Joint Report.

5. *Johnson & Johnson*

Johnson & Johnson and Columbia agree that all of the claims in the *Johnson & Johnson* action that are listed in the Proposed Order should be dismissed without prejudice pursuant to the Court's Order. Additionally, based on Columbia's representations to this Court and Johnson & Johnson, the parties agree that there is no longer a case or controversy with respect to Johnson & Johnson's Fifth Claim for Relief, seeking a declaration that no royalties are owed for activities that occurred solely in the United States based on existence of foreign patents. The parties therefore agree that there are no remaining counts and that this case should be completely dismissed without prejudice pursuant to the Court's November 5, 2004 Order.

B. Which Cases Should Be Completely Dismissed Pursuant To The Court's Order?

1. *Biogen*

a. Position of Biogen and Genzyme

As set forth above, Biogen and Genzyme do not believe that the *Biogen* action should be completely dismissed as to Biogen and Genzyme unless Counts I and V of that action proceed in the *Idec* action. With respect to the counts that should be dismissed pursuant to the Court's Memorandum and Order of November 5, 2004, however, Biogen and Genzyme respectfully request that the Court expressly incorporate the Covenant Not to Sue into any final order of dismissal to ensure that the Court will have subject matter jurisdiction over any disputes regarding the interpretation or enforcement of the Covenant. A proposed form of Order is attached hereto.⁹

⁹ Biogen and Genzyme's original draft of the Proposed Order read, in the second paragraph, "With the consent of the parties, the Court retains jurisdiction" To the surprise of Biogen and Genzyme, Columbia has announced that it does not consent to this

b. Position of Abbott

Abbott agrees that all of Abbott's claims in the *Biogen I* Amended Complaint have been completely dismissed by the Court's Order.

c. Position of Columbia

Columbia maintains that the *Biogen I* action has been completely dismissed by the Court's Order. Columbia also submits that there is no basis to "incorporate" the Covenant Not to Sue into the final order of dismissal. The Court has already explained the meaning and consequence of the Covenant Not to Sue in its November 5, 2004 Order. Columbia also submits that Biogen and Genzyme's request that the Court enter an order retaining jurisdiction over the dismissed claims for purposes of disputes regarding the covenant is unnecessary. To the extent applicable law already grants the Court such jurisdiction, such an order is unnecessary. To the extent applicable law does not grant the court such jurisdiction, such an order would be improper.

2. *Wyeth*

a. Position of Columbia

Columbia maintains that the *Wyeth* action has been completely dismissed by the Court's Order.

3. *Johnson & Johnson*

Johnson & Johnson and Columbia agree that the *Johnson & Johnson* action should be completely dismissed by the Court's Order.

C. What Are The Remaining Cases And Counts?

1. *Amgen:*

a. Position of Amgen and Immunex

The remaining counts brought by Amgen in this action are identified under part (a), above.

Columbia's counterclaim raises four counts, one for breach of contract and one for declaratory relief, against each of Amgen Inc. and Immunex Corporation, respectively, regarding the parties' rights under their license agreements with Columbia. Amgen has raised various defenses to those claims, including allegations regarding Columbia's misconduct in the prosecution of the Axel patents which constitutes "repressive practices"

aspect of the Proposed Order. Columbia's refusal to consent notwithstanding, it is obvious that the Court should retain jurisdiction to enforce the Covenant. It was in reliance on Columbia's Covenant that this Court dismissed certain of plaintiffs' declaratory judgment claims. It is imperative that Columbia be required to comply with the Covenant.

prohibited by those license agreements. These claims should not be remanded to the Central District of California because they include the same transactions and occurrences that led to transfer by the Panel.¹⁰

b. Position of Columbia

The only remaining claims are Columbia's counterclaims for breach of contract and declaratory relief relating to Amgen's failure to pay more than \$125 million in royalties and interest owed under the original Axel patents, and having nothing to do with the '275 patent, the '159 application, or any reissued or reexamined patent. Even if the Court permits Amgen's First and Seventh Claims for Relief to survive based on Amgen's position *du jour* (*i.e.*, that these claims supposedly pertain to Columbia's original, now-expired Axel patents) these claims should be remanded to the Central District of California because they lack any connection whatsoever with the '275 patent, the '159 application, or any common question of law or fact supporting the 28 U.S.C. § 1407 transfer by the Judicial Panel on Multidistrict Litigation ("JPML").

2. *Biogen*

a. Position of Biogen and Genzyme

As set forth above, Counts I and V of the original *Biogen* action remain, along with the *Idec* action in its entirety.

b. Position of Abbott

Not applicable.

c. Position of Columbia

Biogen and Genzyme contend that Count I is not dismissed because they seek a declaration that they owed no royalties at the time Columbia terminated their license agreements for material breach (which has been rescinded). Of course, there is no reference to the termination notice in the actual text of Count I. Even if there were, however, it would be inapposite. In light of Columbia's covenant, there is no longer any dispute between Columbia and the plaintiffs regarding whether they owe royalties under the '275 patent, for either the time period before the termination notice or after. Plaintiffs therefore lack a reasonable apprehension of suit based on a dispute as to whether they owe royalties for the time period before termination. In light of this, Count I cannot satisfy the jurisdictional requirements of the Declaratory Judgment Act.

¹⁰ Columbia's suggestion that the Central District of California had significant experience with Columbia's "repressive practices" is without basis. Although Judge Pfaltzer denied dismissal of the Seventh Claim for Relief, no evidence was presented to her regarding the manipulative acts of double patenting and other misconduct of Columbia that this Court has considered and that are integral parts of Columbia's contractually-prohibited repressive practices.

Plaintiffs want to claim that Columbia's termination of their license agreement was a breach of contract, and they want to seek damages based on this. Count I of the Amended Complaint, which is a pure declaratory judgment claim, has nothing to do with breach of contract. In particular, it contains none of the allegations necessary to plead a contract claim. It does not allege a breach, it does not allege performance by Biogen and Genzyme, and it does not allege damages. If plaintiffs wanted to assert a breach of contract claim in their complaint, they should have pleaded it before their action was dismissed, as Genentech did. For Biogen and Genzyme to suggest that this Court has not disposed of Count I requires a willful misreading of both the November 5 Order and their Amended Complaint.

In addition, the 13th-hour plan of Biogen and Genzyme to salvage their complaint by proposing that they be able to "supplement" it to add a claim for breach of contract and related allegations is improper. At the September 9, 2004 hearing regarding scheduling for Columbia's Motion to Dismiss, counsel for Biogen and Genzyme announced that they planned to "supplement" their *Biogen I* complaint to add a breach of contract claim and related allegations. 9/9/04 Hearing, at 11:18-12:18. This Court responded: "Well, you'd have to move for leave to amend it, and then I'd have to decide if that's contested and, if it's contested, whether the interests of justice make it appropriate." *Id.* at 20:13-16. In the three months that have elapsed since the hearing, plaintiffs have made no attempt to seek leave to supplement their complaint. Now, after the parties have gone to considerable expense briefing Columbia's Motion to Dismiss, and after the Court has *dismissed* the *Biogen I* Amended Complaint in its entirety, Biogen and Genzyme want yet another bite at the apple.

Courts look with disfavor on attempts to amend a complaint after a dispositive ruling resolves the case. *See, e.g., Diersen v. Chicago Car Exchange*, 110 F.3d 481, 489 (7th Cir. 1997) (denying leave to amend after summary judgment) ("we have stated that 'delay in presenting a post-judgment amendment when the moving party had an opportunity to present the amendment earlier is a valid reason for a district court not to permit an amendment.'") (citation omitted); *Vielma v. Eureka Co.*, 218 F.3d 458, 468 (5th Cir. 2000) (denying leave to amend after summary judgment) ("In cases where a party seeks to amend her complaint after entry of judgment, 'we have consistently upheld the denial of leave to amend where the party seeking to amend has not clearly established that he could not reasonably have raised the new matter prior to the trial court's merits ruling.'") (citation omitted); *Briddle v. Scott*, 63 F.3d 364, 380 (5th Cir. 1995) (collecting cases denying leave to amend after resolution of case) ("A busy district court need not allow itself to be imposed upon by the presentation of theories seriatim. Further, after summary judgment is granted, the court has even more reason for refusing to allow amendment.") (citations and internal quotations omitted). Courts recognize that granting leave to amend after the final resolution of a case rewards parties for acting in a dilatory fashion and attempting to game the system. For these same reasons, it would be unjust to allow Biogen and Genzyme to now amend or supplement their completely dismissed complaint.

Finally, the fact that Columbia has moved to dismiss the improperly-filed follow-on complaint, *Biogen Idec, Inc., Biogen Idec MA, Inc., and Genzyme Corp. v. Columbia University*, No. 04cv12009 MLW ("*Biogen II*"), does not justify allowing Biogen and

Genzyme to supplement or amend their complaint in *Biogen*.¹¹ Columbia's motion to dismiss *Biogen II* argues that Biogen and Genzyme should have requested leave to file their breach of contract and related claims via a Rule 15 motion in the *Biogen I* action. Biogen and Genzyme refused to do so. They made the strategic decision to rest their hopes on the improperly-filed *Biogen II* complaint. They must now face the consequences. *Biogen II* was improperly filed, and it should be dismissed. In addition, the time to supplement or amend the *Biogen I* action has passed.

3. *Genentech:*

a. Position of Columbia.

The only remaining claim is Genentech's Fifth Claim for breach of contract.

D. Prospects For Settlement Of Remaining Cases And Proposed Schedules For Doing So?

1. *Amgen*

a. Position of Amgen and Immunex

Amgen denies Columbia's claim to any further royalties because no royalties are owed. (Indeed, even Columbia has not presented a claim for anything like \$125 million.) The parties have engaged in substantial settlement discussions, without resolution of this dispute. While Amgen sees no need that a period of time be set aside solely for continuation of settlement discussions, Amgen believes it could be productive to engage in a mediation under Section II(B) of the Court's Alternative Dispute Resolution Plan.

b. Position of Columbia

The parties have had very recent discussions regarding the more than \$125 million that Amgen owes Columbia in back royalties and interest on the original Axel patents, but have been unable to make any progress in resolving this issue. Columbia does not believe that further settlement discussions would be productive at this time, and believes that future settlement discussions will have to await the production and analysis of Amgen's inventory, financial, and other internal records during the course of formal discovery on Columbia's counterclaims. Columbia does not believe that a schedule for conducting settlement discussions would be helpful at this juncture.

2. *Biogen*

a. Position of Biogen, Genzyme, and Columbia.

¹¹ Columbia has moved to dismiss *Biogen II* because it is duplicative of the *Biogen I* action, because it circumvents the procedures for amending and supplementing pleadings under Federal Rule of Civil Procedure 15, and because it evades the Court's instruction to add new allegations regarding Columbia's conduct via a motion to amend.

Biogen, Genzyme, and Columbia do not believe that any alteration of the schedule is required to accommodate further settlement negotiations.

b. Position of Abbott

Not applicable.

3. *Wyeth*

a. Position of Columbia

Columbia believes that all claims in the *Wyeth* case have been dismissed. The parties have had recent discussions, however, regarding a comprehensive resolution of their differences. These discussions are ongoing.

4. *Genentech*

a. Position of Columbia

Although the parties have had some settlement discussions, the parties are very far apart in their respective proposals. Columbia does not believe that there is any reasonable prospect for settlement with Genentech.

5. *Johnson & Johnson*

Columbia and Johnson & Johnson believe that all claims in the *Johnson & Johnson* case should be dismissed. In addition, Columbia and Johnson & Johnson have signed an agreement in principle to settle the current dispute.

E. Should A Stay Concerning Any Or All of The Remaining Cases And Claims Be Entered?

1. Position of Amgen and Immunex

Amgen does not believe that the remaining claims should be stayed.

Amgen further notes that Columbia's exclusion of Amgen's affiliates from its Covenant Not To Sue (the "Covenant") has the effect of leaving Columbia's threats of enforcement of the '275 patent active as to Amgen's affiliates, and threatens their current activities. Amgen's affiliates are in process of filing their own claims against Columbia to address this issue, and we expect those claims will be transferred to this Court soon. It would be inappropriate to stay those claims for the same reasons stated in this Court's Memorandum and Order of August 16, 2004, denying Columbia's motion to stay.

2. Position of Biogen and Genzyme

Biogen and Genzyme do not believe that a stay of any of their remaining claims would be appropriate or efficient.

3. Position of Abbott

Not applicable.

4. Position of Johnson & Johnson

Not applicable.

5. Position of Columbia

Columbia does not believe that there should be any stay of any of the remaining cases or claims. Rather, Columbia reiterates that the few remaining claims should be remanded to their respective district courts of origin, now that the common factual and legal questions supporting this multidistrict litigation proceeding have been vitiated.

Genentech seeks a stay of its remaining claim to allow it to conduct settlement discussions with Columbia. Columbia does not believe that a stay will facilitate resolution of its dispute with Genentech. The parties are very far apart in their respective settlement positions, and Columbia does not believe that there is any reasonable prospect for settlement.

F. Recommended Schedule For Resolving The Remaining Cases and Claims If A Stay Is Not Entered.

1. *Amgen*

a. Position of Amgen and Immunex

The Amgen affiliates' claims (which have not been included in Columbia's Covenant) should also be combined in these proceedings. Accordingly, a schedule for those issues in common with the other plaintiffs would be in order. Amgen suggests:

- Last day to file motions to amend unless based on newly-discovered evidence: December 31, 2004.
- Automatic disclosures under Local Rule 26.1(B)(1) and (2) and 26.2(A): February 15, 2005
- Fact discovery to close by June 15, 2005.
- Opening expert reports due by July 15, 2005.
- Rebuttal expert reports due by August 7, 2005.
- Expert discovery to close by August 31, 2005.
- Opening briefs on dispositive motions and on claim construction: September 15, 2005.

- Opposition briefs on dispositive motions and on claim construction: September 29, 2005.
- Reply briefs on dispositive motions and on claim construction: October 6, 2005.
- Dispositive motions and claim construction to be heard by October 30, 2005.
- Pretrial Conference: approximately two weeks before trial.
- Trial: November, 2005.

b. Position of Columbia

Amgen is inexplicably proposing above a schedule that takes into account a lawsuit by Amgen's affiliates that has not yet been filed in this Court or anywhere else, let alone transferred to this Court by the JPML or otherwise. Amgen also asserts above, without any support, that it has "issues in common with the other plaintiffs." If anything is clear from this Joint Report, it is that there are no factual or legal issues that any plaintiff has in common with any other plaintiff.

As noted above, the only remaining claims in the *Amgen* lawsuit are Columbia's counterclaims seeking more than \$125 million in back royalties under Columbia's now-expired, original Axel patents. Indeed, even if the Court permits Amgen's First and Seventh Claims for Relief to survive, Amgen has now made clear that these are declaratory relief claims mirroring Amgen's defenses to Columbia's counterclaims.

All of the remaining *Amgen* claims are unique to this lawsuit. Of all the plaintiffs in this litigation, *only* Amgen took the position that it did not have to pay royalties for product manufactured before August 16, 2000 but sold after that date. As a result, Amgen is the only plaintiff that Columbia is counter-suing for payment of past due royalties under its original three Axel patents. This issue is not raised in any of the other lawsuits, it is not relevant to the enforceability or validity of the '275 patent or the '159 application, and Amgen does not claim otherwise.

The express basis for the transfer order by the JPML pursuant to 28 U.S.C. § 1407 was the presence of common questions relating to the *validity and enforceability of the '275 patent*. Because these common questions no longer exist, let alone predominate, this Court should enter an order suggesting that the JPML remand the *Amgen* and *Genentech* cases to the districts in which they originated, as requested in Columbia's Motion to Dismiss.

A schedule for the resolution of Columbia's counterclaims should therefore be implemented only after this Court and the JPML have had an opportunity to rule on the remand issue.

2. *Biogen*

a. Position of Biogen and Genzyme

In view of the uncertainty concerning which cases and claims will be dismissed as a result of the Court's November 5, 2004 Memorandum and Order, and the uncertainty arising from Columbia's request that various remaining claims be remanded to other courts, Biogen and Genzyme respectfully request that they be permitted to propose a schedule after the Court resolves those uncertainties.

b. Position of Abbott

Not applicable.

c. Position of Columbia

Columbia maintains that there are no claims remaining in the *Biogen I* case. Until the Court resolves the dispute between Biogen, Genzyme and Columbia on this issue, Columbia believes it is premature to discuss scheduling.

3. *Wyeth*

a. Position of Columbia

Columbia maintains that there are no claims remaining in the *Biogen I* case. Until the Court resolves the dispute between the parties on this issue, Columbia believes it is premature to discuss scheduling.

4. *Genentech*

a. Position of Columbia

As discussed above, Columbia believes that the remaining claim in the *Genentech* action should be remanded to the Northern District of California. Genentech's remaining claim for breach of contract revolves around unique allegations that were not the basis for 28 U.S.C § 1407 transfer.

Respectfully submitted,

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